ARIZONA AIDS DRUG ASSISTANCE PROGRAM VALGANCICLOVIR USE GUIDELINES JANUARY 2004

Valganciclovir has been approved by the Formulary Committee for use in selected ADAP clients. Valganciclovir has been shown to be as effective as intravenous ganciclovir in the management of cytomegalovirus (CMV) infection in patients infected with HIV. The most recent USPHS/IDSA Guidelines for the Prevention of Opportunistic Infections in Persons Infected with Human Immunodeficiency Virus (www.aidsinfo.nih.gov/guidelines/) recommend the use of valganciclovir to prevent the recurrence of CMV infection in patients with prior end-organ disease. These guidelines do not recommend the use of valganciclovir for primary prophylaxis in patients with HIV.

Because of the high acquisition cost of valganciclovir (approximately \$15,000 per patient per year), the Formulary Committee will require that prescribers provide ADAP with selected patient data. Periodic review of these data will allow a better assessment of the use of this agent.

Indication: Secondary prevention of CMV infection in patients with documented prior endorgan CMV disease (e.g. retinitis, colitis). Most patients will have a CD4 count <50.

Dose (for secondary prevention): Based on the patient's renal function (calculated creatinine clearance; Clcr (males, ml/min) = (140-age)(Weight in Kg) (X 0.85 for female) (72)(serum creatinine)

CICr (ml/min)	<u>Dose</u>
>60	900mg qd
40-59	450mg qd
25-39	450mg every other day
10-24	450mg twice weekly
<10	Not recommended
Dialysis	Not recommended

Duration of therapy: Consideration for the discontinuation of valganciclovir therapy should be given in patients receiving HAART with a sustained (>6 month) increase in CD4 count to >100-150. These patients should have no evidence of active CMV disease and be able to undergo regular ophthalmologic examinations.

PATIENT DATA REQUIRED (complete the valganciclovir application)

Client name

Date of application

Indication for valganciclovir

How was CMV disease documented?

Valganciclovir dose

Most recent serum creatinine, date of measurement

Calculated creatinine clearance

Most recent CD4 count, date of measurement

Most Recent viral load, date of measurement

Most recent white blood cell count, hemoglobin/hematocrit, platelet count, date of measurement